12

EUROPEAN PATENT APPLICATION

(21) Application number: 84306430.4

6 Int. Ci.4: A 61 J 3/07

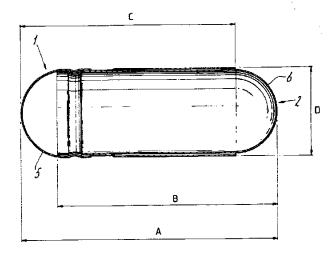
② Date of filing: 20.09.84

30 Priority: 23.09.83 GB 8325529

Applicant: Lilly industries Limited, Lilly House Hanover Square, London W1R 0PA (GB)

- (3) Date of publication of application: 05.06.85 Bulletin 85/23
- Inventor: Jones, Brian Eliwood, 25 Richmond Road, Basingstoke Hampshire (GB)
- Designated Contracting States: AT BE CH DE FR GB IT LI LU NL SE
- (4) Representative: Hudson, Christopher Mark et al, Erl Wood Manor, Windlesham Surrey GU20 6PH (GB)

- 5 Two-part capsule.
- There is described a two part capsule composed of rigid material readily soluble when ingested, preferably gelatin, which capsule comprises a cap and body, both of which are of cylindrical form and roundedly closed at one end and open at the other, the body being telescoped within the cap to form a closed container, the relative lengths of the cap and body being such that only the closed rounded end of the body protrudes externally from the cap, the ratio of the length of the capsule to the diameter of the cap being in the range of from 2.5–3.5 to 1.



EP 0 143 524 A1

for containing medicaments.

5

10

15

20

25

MEDICINAL FORMS

-1-

This invention relates to a two part capsule suitable

Two part capsules made of gelatin, or of some other similarly rigid film-forming material readily soluble in the body, are conventionally composed of a cylindrical open ended body portion closed by a cap which telescopes over the open end In the conventional capsule, the cap is approxof the body. imately half as long as the body so that part of the latter's length is left exposed and the two parts, body and cap, can be Locking facilities, in the form of mutually drawn apart. engaging grooves or recesses in the cap and body are generally provided to avoid easy or accidental separation of the two These facilities, however, are frequently insufficient parts. to prevent deliberate manual separation, and cases have been reported of such separation for the purpose of illicit tampering with the capsule contents. An object of the present invention is to provide a two part capsule, the construction of which renders such manual separation impossible or more difficult.

Thus, the invention provides a two part capsule composed of rigid material readily soluble when ingested, preferably gelatin, which capsule comprises a cap and body, both of which are of cylindrical form and roundedly closed at one end and open at the other, the body being telescoped within the cap to form a closed container, the relative lengths of the cap and body being such that only the closed rounded end of the

body protrudes externally from the cap, the ratio of the length of the capsule to the diameter of the cap being in the range of from 2.5-3.5 to 1.

By assembling the two parts of the capsule so that 5 only the closed rounded end of the body is exposed, insufficient cylindrical surface of the body is presented to enable the purchase necessary for manual separation of the two parts and by the suitable choice of the dimensions of cap and body, a tamper-resisting capsule is therefore obtained which, moreover, 10 retains the overall shape of conventional capsules that have gained acceptance from patients over a considerable period of time. The dimensions may also be such that machinery required in manufacture and filling need only be adapted to produce or handle the longer cap, since the body portion can be of standard 15 dimensions. Such production machinery can be of the usual kind in this art, with pins which are dipped into fluid gelatin, methyl cellulose, cellulose acetate or other suitable film material, the walls of the cap and body preferably being of equal thickness throughout.

The closed ends of the cap and body are preferably hemispherical but other suitable, generally rounded, shapes can also be employed. Thus, only the hemispherical portion of the body protrudes from the cap, so that no portion of the cylindrical part of the body is exposed to provide a grip by which the two parts of the capsule can be drawn apart.

The cap and body are preferably of the same length so that the open end of the body portion abuts against the closed end of the cap. Other dimensions are possible, however,

5

10

15

provided that they allow the body to fit within the cap with only its end protruding. The ratio of the length to diameter of cap is preferably in the range of 2.1-2.6 to 1, for example from 2.3-2.45 to 1 and that of the body preferably in the range of 2.2-2.7 to 1, for example from 2.4-2.6 to 1. It should be noted that when dimensions of capsule, cap and body are mentioned it is the external dimensions that are intended.

We have found that the ratio of cap length to the overall length of the capsule is preferably from 0.8-0.9 to 1, such as from 0.82 or 0.85-0.9 to 1.

The invention is illustrated by way of example with reference to the accompanying Drawings, in which:

Figure 1 is a partial sectional view of one embodiment of a two part capsule according to the invention;

Figure 2 is a view of the cap of the capsule illustrated in Figure 1; and

Figure 3 is a similar view of the body of the capsule illustrated in Figure 1.

The capsule comprises a cap (1) and body (2) both

comprising a cylindrical portion (3 and 4 respectively) and a

closed end portion (5 and 6 respectively) which is of hemispherical
shape.

The cap is seen more clearly in Figure 2 and is of the type that includes a shallow annular shoulder (7) and annular groove (8) towards its closed end (5). The cap can be tapered from its open end. The body (Figure 3) bears a corresponding annular groove (9) towards its open end (10), which is positioned so that when the capsule is assembled in

its final locked position and the two annular grooves (4 and 9) are engaged as seen in Figure 1, only the hemispherical closed end of the body (6) protrudes.

The shallow annular shoulder (7) allows the cap and 5 body to be loosely fitted together for storage or transport before the filling operation takes place and is positioned such that sufficient of the surface of the cylindrical portion is exposed to permit disengagement from the cap in preparation for the filling operation. Thus when assembling the cap and body 10 for transport before the filling operation, the open end of the body is slid within the cap as far as the annular shoulder (7) against which the open end (10) of the body lightly abuts and is held from further engagement. After disengagement and the filling operation, the cap and body can be engaged once more 15 and the body slid past the annular shoulder (7) so that the grooves (8 and 9) lock together.

With regard to the dimensions of the capsule, the overall external length (A) (Figure 1) of the assembled capsule and the external diameter of the cap (D) are in the ratio of 2.5 to 3.5 to 1 preferably in the range of 2.7 to 3.0, to 1. The length (B) of the body and the length (C) of the cap are substantially equal and the diameter of the body is such as to provide sliding engagement within the cap.

Examples of the dimensions of capsules according to the invention are as follows:

25

	<u>Size*</u>	Capsule	Body		<u>Cap</u>		<u>Volume</u>
		mm	mm		mm		cc
		length	length	diameter	length	diameter**	
5		(A)	,	(B)		(C)	
	0	21.8	18.6	7.33	18.6	7.63	0.67
	1	19.5	16.5	6.62	16.5	6.90	0.48
	2	17.8	15.1	6.07	15.1	6.35	0.37
10	3	15.9	13.5	5.56	13.5	5.82	0.27
	4	14.5	12.3	5.06	12.3	5.32	0.20

^{*} international size

15 It will be appreciated that the invention has been described in relation to a preferred type of capsule, and many variations are possible. For example, the capsule cap and body need not posses the particular combination of grooves and shoulder as shown in the Drawings. Moreover, the length of the cap need not be equal to that of the body provided it is long enough to provide sufficient cover for the body.

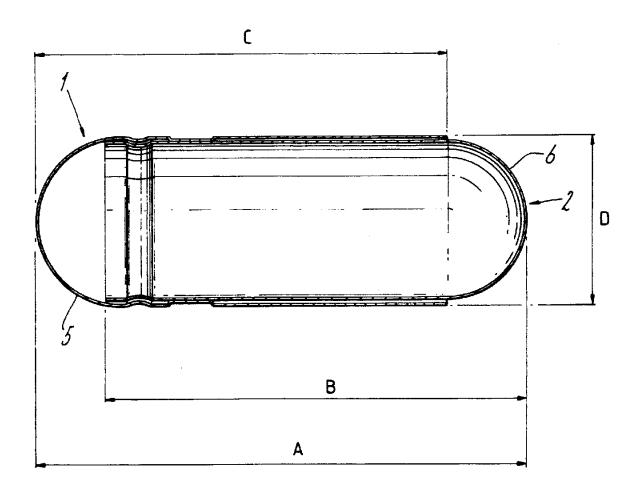
A preferred capsule of the invention is one in which the cap has an annular groove towards its closed end and the body has a corresponding annular groove near its open end, the grooves being so positioned that in the assembled capsule they lock together and only the closed end of the body protrudes from the cap.

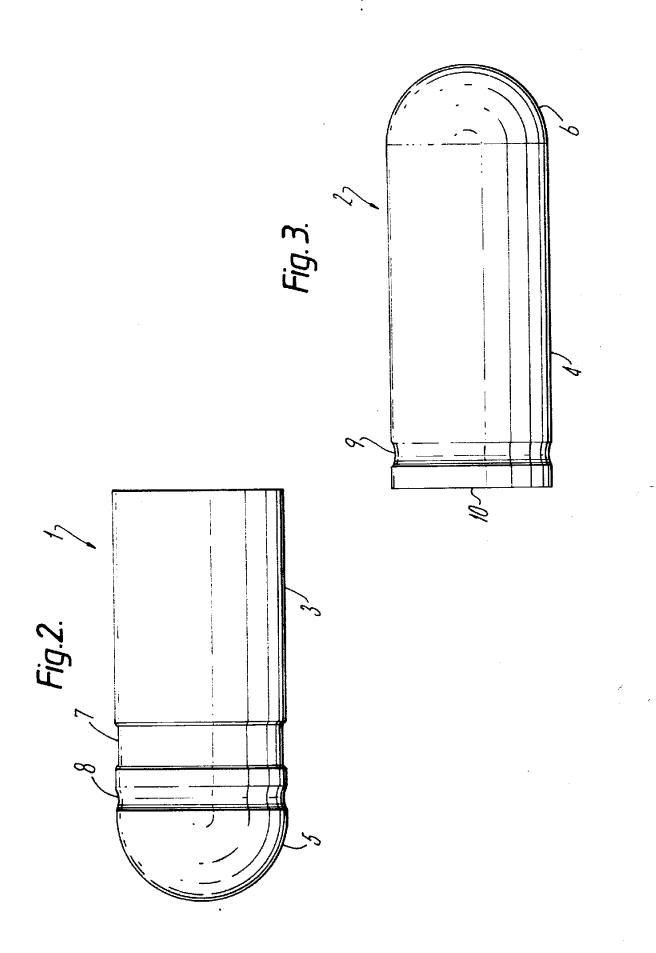
^{**} does not take into account taper

CLAIMS

- 1. A two part capsule composed of rigid material readily soluble when ingested, preferably gelatin, which capsule
- 5 comprises a cap and body, both of which are of cylindrical form and roundedly closed at one end and open at the other, the body being telescoped within the cap to form a closed container, the relative lengths of the cap and body being such that only the closed rounded end of the body protrudes externally from the cap, the ratio of the length of the capsule to the diameter of
- 10 the cap being in the range of from 2.5-3.5 to 1.
 - A capsule according to claim I in which the closed ends of the cap and body are hemispherical.
- A capsule according to either of claims 1 and 2 in 3. 15 which the ratio of cap length to capsule length is from 0.8-0.9 to 1.

Fig.1.





EPO Form 1503 03 82

EUROPEAN SEARCH REPORT

0143524

EP 84 30 6430

Category	Citation of document w	rith indication, where appropriate,	Relevant	CLASSIFICATION OF THE	
	OI 181	evant passages	to claim	APPLICATION (Int. Cl.4)	
Y	FR-A-1 461 033 CORP.) * Figure 1; cla		1	A 61 J 3/0	
A			2		
Y	CO.)	 (ELI LILLY AND nes 53-62; figures	1		
A	FR-A-1 153 998 CORP.) * Figure 3 *	 (R.P. SCHERER	1,2		
P,A	EP-A-0 110 500 CO.) * Figures 1,2;	 (WARNER-LAMBERT claims 1, 2 *	1,2	TECHNICAL FIELDS SEARCHED (Int. CI.4) A 61 J 3/07	
	The present search report has b	een drawn up for all claims]		
	Place of search BERLIN	Date of completion of the search 14-12-1984	BARNY	Examiner DE ROMANET P.M	
Y: part doci A: tech	CATEGORY OF CITED DOCU icularly relevant if taken alone icularly relevant if combined w iment of the same category nological background written disclosure	E : earlier par after the f th another D : documen L : documen	iting date t cited in the appli t cited for other re	ut published on, or	